K063345

510(k) Summary

JAN 12 2007

Trade Name: SPY® Imaging System

Model Number: SP2000

Common Name: Fluorescent Angiographic System

Classification: 21 CFR 892.1600

Product Code: 90 IZI

Classification: Class II

Manufacturer: Novadaq Technologies Inc.
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Mississauga, Ontario
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Contact Name: Allison Manners
Vice President – Regulatory and Clinical Affairs

Date 510(k) Summary Prepared: November 2, 2006

Legally Marketed Predicate Devices:

The Novadaq® SPY Imaging System had received FDA 510(k) clearance for market in January 2005 (K#042961) and subsequently 510(k) clearance for a labeling change in May 2006 (K#060867).

The Leica FL800 had received FDA 510(k) clearance for market in September 2006 (K#061871). The Leica FL800 is intended for use to allow neurosurgeons to view blood flow.

Device Description:

The SPY Imaging System: SP2000 is currently cleared for use for intra-operative visual assessment of the coronary vasculature and grafts during coronary artery bypass graft (CABG) surgery.

The Novadaq® Technologies SPY® Imaging System consists of 2 components:

- the SPY Imaging Device; and
- the SPY Paq™

The SPY Paq is comprised of:

- 6 Novadrape™ custom sterile drapes; and
- 1 box of IC-Green™ (Indocyanine Green-ICG) imaging agent that contains 6 x 25 mg vials of IC-Green and 6 x 10 ml ampules of sterile Aqueous Solvent.

The IC-Green is supplied intact as received and labeled from the manufacturer of the product.

The SPY Imaging Device

The SPY Imaging Device consists of an imaging head containing a charge coupled device (CCD) camera, a laser light source, motion sensor and distance sensor attached via an articulating arm to a mobile cart. The mobile cart contains a flat panel display, computer, electronics enclosure and printer.

The SPY System provides the surgeon with the capability to view record and replay fluorescent images of blood flow in vessels and bypass grafts of the heart. A laser light source is used to illuminate the heart surface. IC-Green™ (indocyanine green) is injected intravenously through the central venous line, bypass pump, cardioplegia line and aorto coronary graft and while it is passing through the vessels, the absorption of laser light causes excitation of the dye followed by emission of infrared energy. The result is a fluorescent image of the coronary vasculature. A CCD camera captures the image. These images are used to evaluate the integrity of the coronary vasculature and blood flow in the heart and bypass grafts.

There have been no significant changes or modifications made to the SPY Imaging device since the original 510(k) clearance in January 2005, premarket notification 510(k) K#042961, or for the 510(k) submitted for a label change for this device, K#060867.

This 510(k) submission describes a proposed change in intended use that does not alter the devices fundamental scientific technology or characteristics in anyway.

Proposed Intended Use of the SPY System:

Please note that the currently cleared indication for use in CABG surgery is not being amended in anyway with this submission.

This premarket notification 510(k) application is being made to add an additional indication for use for the SPY® System.

In addition to the already cleared indication for use of the SPY System, the SPY System is an imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.

Testing:

Animal studies, human experience and *in vitro* testing were conducted to support the safe and effective use of the SPY System in its original premarket notification 510(k) application (K#042961).

In Vitro Testing:

Testing of the SPY System was completed in conformance with the following standards. The SPY System successfully met all of the requirements for these standards.

1. Electrical per IEC 60601-1 and UL2601-1
2. Electromagnetic Compatibility per IEC 60601-1-2
3. Light Emitting Laser Products per 21 CFR 1040
4. Safe Use of Lasers in Health Care Facilities per ANSI Z136.3
5. American National Standard for Safe Use of Lasers per ANSI Z136.1

In Vivo Testing:

The SPY System is commercially available in the United States of America, Japan, Europe and Canada. To date, the SPY System has been used in over 4000 CABG procedures in humans and there have been no reports of adverse acute or long-term cellular, renal or hepatic effects. Along with the data from intra-operative imaging in CABG surgery, the use of the SPY System in plastic, micro- or reconstructive surgery demonstrates the clinical utility of the device in producing high quality and resolution images of the entire vascular bed of the point of interest.

In the proposed indications for use in this application, the SPY® images were useful in determining not only the relative perfusion of the flap for harvest prior to incision, but also in reconstructive surgery, the blood flow in the native vessels to provide insight as to whether there is sufficient perfusion to support the reconstruction and the inset of a free flap. The SPY System has also been used intra-operatively to visually assess blood flow in the native artery and vein related to the flap and post reconstruction to assess anastomotic integrity and tissue-transfer circulation. The images provided in Section 19 – Clinical, of this

application demonstrate the use of the fluorescent images in assessing blood flow, post surgical closure, in a non-body contact manner to aid medical staff in assessing flap viability post surgery, along with other standard practices, such as evaluation of flap color, temperature, time for recapillarization and bleeding after puncture.

Results from the use of the SPY System has been the subject of 12 peer reviewed journal articles, 10 related to its use in cardiac surgery and 2 related to its use in transplantation surgeries, namely kidney and liver. Please refer to the bibliography in Section 19 - Clinical for a listing of all relevant journal articles.

The literature reports that the SPY System was able to non-invasively, quickly and safely identify 17 conduits in 311 patients that required revision during the surgical procedures. In all cases the lack of patency was visualized clearly by the SPY System using doses of IC-Green™ well below that approved for human use, allowing the surgeon to revise the graft thus decreasing subsequent myocardial infarctions and the morbidity and mortality associated with poor graft patency. Cardiac, renal and hepatic function were monitored during use of the SPY System and there were no reported adverse effects.

To support the original premarket notification 510(k) application, the system was used in six pig studies. These studies demonstrated that:

1) it was possible to acquire high quality images in a simple and reproducible manner using small doses of IC-Green well below the concentrations approved for human use;
2) it was possible to perform multiple imaging sequences with no detrimental effects on heart function, coronary flow or peripheral pressure; and
3) it was possible to acquire images with no increase in myocardial tissue temperature; and
4) it was possible to visualize all of the coronary beds with high quality images even when the heart was in a vertical position for visualizing posterior arteries.

Therefore, the *in* vivo evidence shows that:

1. The exposure for the SPY® System is 35 mW/cm^2 which is far below the maximum permissible exposure of 327 mW/cm^2 established by ANSI for exposure to the skin.
2. Use of the SPY System does not cause any thermal damage to the area of interest, even after repeated imaging sequences.
3. For the heart, there were no changes in electrocardiograms or arterial pressures during and/or following SPY use.

4. There were no acute or long-term cellular effects of using the SPY System.
5. There were no acute or long-term renal or hepatic effects of using the SPY System.
6. The SPY System was able to acquire high quality images of the entire vascular bed on each area of interest.
7. The SPY System is capable of imaging through the skin to provide a visual assessment of dermal and subdermal blood flow.

Conclusions:

The above testing demonstrates that the SPY Imaging System is safe and effective in imaging blood flow indicative of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures and is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JAN 12 2007

Re: K063345
Trade/Device Name: SPY® Imaging System
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: Class II
Product Code: IZI
Dated: November 3, 2006
Received: November 6, 2006

Dear Ms. Manners:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

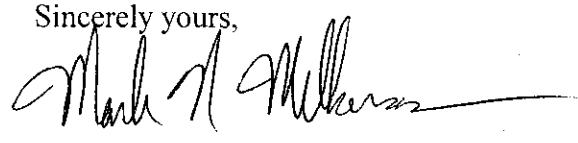
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063345

Device Name: SPY® Imaging System: SP2000

Indications for Use:

The SPY System is an imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063345